ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2019-0178; FRL-10023-89-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Ethylene Oxide Commercial Sterilization Facilities National Emission Standards for Hazardous Air Pollutants (NESHAP) Technology Review

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice

SUMMARY: The U.S. Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Ethylene Oxide Commercial Sterilization Facilities National Emission Standards for Hazardous Air Pollutants (NESHAP) Technology Review (EPA ICR Number 2623.01, OMB Control Number 2060-NEW), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). This is a request for approval of a new collection. Public comments were previously requested via the *Federal Register* on June 12, 2020, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A complete description of the ICR is provided below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA-HQ-OAR-2019-0178, online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be

Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Witosky, Sector Policies and Programs Division (E143-05), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2865; email address: *witosky.matthew@epa.gov*.

SUPPLEMENTARY INFORMATION:

Supporting documents explaining in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *https://www.regulations.gov/*. The telephone number for the Docket Center is (202) 566-1742. For additional information about EPA's Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

Abstract: The NESHAP for EtO Commercial Sterilization and Fumigation Operations were finalized in December 1994 at 40 CFR part 63, subpart O. The NESHAP establishes emission standards for both major and area sources that use at least 1 ton of EtO in sterilization or fumigation operations in any 12-month period. The standards require existing and new major sources to control emissions to the level achievable by the maximum achievable control technology and require existing and new area sources to control emissions using generally available control technology. The EPA completed a residual risk and technology review for the NESHAP in 2006 and, at that time, concluded that the risk under existing standards were acceptable and provided an ample margin of safety. More recently, in 2016, the EPA released its updated Integrated Risk Information System unit risk estimate for EtO, which indicated that cancer risks from EtO were significantly higher than previously understood. Subsequently, the

National Air Toxics Assessment (NATA) released in August 2018, identified EtO emissions as an important risk driver in several areas across the country. Further investigation revealed the EtO Commercial Sterilization source category contributes to some of these risks, which has led the EPA to evaluate, in greater depth, potential options to reduce emissions of EtO from the source category.

Since 2019, the EPA has been gathering additional information to evaluate opportunities to reduce EtO emissions through potential rule revisions and more immediate emission reduction steps. The goal of the data gathering efforts is to better understand the emissions sources, measurement and monitoring techniques, and available control technologies and their associated efficiencies. These efforts have included an advance notice of proposed rulemaking (ANPRM) requesting facility-specific data on process controls and operational practices as well as a CAA section 114 questionnaire that was distributed to 9 companies engaged in EtO commercial sterilization. The instructions and questionnaire were posted to the EPA webpage where they were accessed by facilities. Electronic responses were required within 60 days or by February 6, 2020. While these data gathering efforts have been successful, there are still several important information gaps that should be filled prior to any final rulemaking activity. Therefore, the EPA is now exercising its authority under section 114(a) of the CAA to broaden its data collection efforts to include all facilities subject to 40 CFR part 63, subpart O that were not involved in the December 2019 questionnaire. The data collected through the initial questionnaire and this new ICR would enable the EPA to have a complete understanding of all emissions, emissions sources, processes, and control technologies in use at EtO sterilization facilities nationwide, providing a robust foundation for a final rulemaking.

Form numbers: Main Questionnaire; Supplement 1 (as needed); Supplement 2 (as needed); Supplement 3 (as needed).

Respondents/affected entities: Facilities subject to 40 CFR part 63, subpart O that are not included in the initial December 2019 questionnaire.

Respondent's obligation to respond: Responses to the ICR are mandatory under the authority of section 114 of the CAA. All respondents are required to fill out the main questionnaire, while Supplements 1, 2, and 3 may be filled out as needed.

Estimated number of respondents: 61 (total).

Frequency of response: This is a one-time questionnaire.

Total estimated burden: 6,573 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: $604,027 (per year), includes $920 annualized capital or operation & maintenance costs.

Changes in the Estimates: This is a new collection. Therefore, there is no change in burden.

Courtney Kerwin,
Director, Regulatory Support Division.
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